Investigator Inspection
Readiness for Health Authority Inspections

CRP Information Session
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Agenda

- Background on FDA Bioresearch Monitoring (BIMO) Inspection Program and European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) Inspection Program
- What is “Inspection Readiness”? 
- Communication Plan
- Role of Site Investigator and Sponsor
- Inspection Process Overview
- Tips for Interacting with Inspectors
- Inspection Findings and Response
Purpose of the FDA BIMO Inspection Program

A comprehensive, agency-wide program of on-site inspections and data audits designed to monitor all aspects of the conduct and reporting of FDA-regulated research

BIMO Program Objectives

- Protect the rights, safety, and welfare of human research subjects
- Assure the quality, reliability, and integrity of data collected
Purpose of Good Clinical Practice (GCP) Inspections – EMA CHMP Authorized Inspections

Collectively allows the EMA to:

- Ensure new medicines are approved based on sound scientific data generated from clinical studies
- Ensure data submitted are reliable and accurate
- Determine whether patients' rights are protected
- Ensure regulatory/GCP requirements are fulfilled
Inspection Readiness Defined

Inspection Readiness is a state of "readiness". It is on-going effectiveness and suitability monitored through periodic review and monitoring of compliance.

- Inspection readiness should be a state of being and not a preparation activity.
- Principal Investigators and management need to be active participants in a commitment to a culture of compliance.
Communication Plan in the Event of Inspection Notification cont.

Alliance and/or its pharmaceutical partner will:

- Provide additional instructions and guidance in preparation for the inspection
- Provide a single point of contact (SPoC) at Alliance for any issues that may arise during the inspection
  - The Alliance SPoC requests to receive a daily report from the site
- The SPoC will assist in the preparation of a response to the inspection results, as needed
Site Inspection Focus (FDA)

- Site Management
- PI Oversight
- Data
- Investigational Product Management
- Adverse Events
Inspection Process- Overview

Overall, the HA inspector will set the visit agenda

- Notification of inspection Form 482 will be received
- Opening Meeting
- Interview of site staff
- Review of study-related documentation and source data

- Exit meeting
  - Review inspection findings
  - Clarify and/or address issues or concerns

- Response to the inspection, as needed
Role of the Investigator During the Inspection

- Ensure the availability of staff during the inspection
  - Alert other staff members of inspection, so that they know to avoid lingering in areas hosting the inspection and to watch conversations near areas where inspectors are present
- Ensure the availability of study-related records and provide copies to HA as requested
- Answer questions regarding your role and the conduct of the study
- At the end of each day, request a summary from the HA Inspector regarding any issues identified and requests to be fulfilled. Forward summary to the Alliance SPoC and the appropriate study email at the Alliance
- Respond to any inspection findings, as required
Role of the Alliance During the Inspection

- Assign a SPoC to the Clinical Site
- Provide a daily status report to pharmaceutical partner(s)
- Provide ongoing support to Clinical Site/Investigator before, during, and after the inspection
Tips for Interacting with the HA Inspectors

When answering questions posed by the inspector:

- Answer as honestly and openly as you can
- Be concise; Answer only the question asked
- Try to be as clear as possible
- Do not argue with the inspector
- Do not answer hypothetical questions
- Do not answer a question until you have heard and understood the whole question
- Beware of pauses – Do not feel like you need to keep on talking
Inspection Findings

The criticality of the inspection findings will be determined based on whether the deficiencies:

- Affect the rights, safety or welfare of the subjects
- Impact the integrity of the data
- Indicate systemic problems within the study from the Sponsor
- Indicate problems with the investigator/site that may impact other studies

FDA Form 483 “Inspectional Observations” is used to document and communicate concerns discovered during inspections. If received, please forward immediately to the Alliance SPoC.
Key Points

- Inspection “readiness” at all times. It isn’t a preparation activity but rather a state of “readiness”
- Alliance and the Pharmaceutical Partner(s) are available to assist in the preparation, participation and close out of the inspection process
- Forward any HA communication to the Alliance IMMEDIATELY:
  - Contact Trini Ajazi, CAO, at tajazi@uchicago.edu and copy regulatory@alliancenctn.org; Alliance Chicago main line: 773-702-9171
- Understand and prepare for your role in the inspection
- Review the tips for interacting with the inspectors
Resources

Visit the suggested links to learn more about inspection programs:

- http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/ucm133562.htm
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Thank you for your participation!